



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1137]

GlaxoSmithKline LLC; Withdrawal of Approval of the Indication for Treatment of Patients with Relapsed or Refractory, Low Grade, Follicular, or Transformed CD20 Positive Non-Hodgkin's Lymphoma Who Have Not Received Prior Rituximab; BEXXAR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the indication for treatment of patients with relapsed or refractory, low grade, follicular, or transformed CD20 positive non-Hodgkin's lymphoma who have not received prior rituximab, for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection held by GlaxoSmithKline LLP, P.O. Box 5089, 1250 South Collegeville Rd., Collegeville, PA 19426 (Glaxo). Glaxo has voluntarily requested that approval of this indication be withdrawn and has waived its opportunity for a hearing.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6250, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: FDA approved BEXXAR on June 27, 2003, for the treatment of patients with CD20 positive, relapsed or refractory, low-grade, follicular, or transformed non-Hodgkin's lymphoma who have progressed during or after rituximab therapy.

On December 22, 2004, FDA approved a new indication to include patients who have not received prior rituximab (the rituximab-naïve indication) under the Agency's accelerated approval regulations for biological products, 21 CFR part 601, subpart E.

On December 13, 2011, FDA requested that Glaxo voluntarily withdraw the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection because the postmarketing study intended to verify clinical benefit and required as a condition of approval under part 601, subpart E was not completed. Withdrawal of approval of the rituximab-naïve indication does not otherwise affect the approved indication for BEXXAR.

On April 23, 2012, Glaxo submitted a prior approval labeling supplement requesting removal of the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection from the package insert. In the cover letter accompanying the supplement, Glaxo requested that FDA withdraw the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection from the market and waived its opportunity for a hearing. In a letter dated May 11, 2012, FDA acknowledged receipt of the prior approval labeling supplement and Glaxo's request to withdraw the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection. Glaxo's labeling supplement was approved by FDA in a letter dated August 15, 2012.

Therefore, under section 506 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 356) and § 601.43, and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection is withdrawn as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Dated: October 18, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2013-24840 Filed 10/22/2013 at 8:45 am; Publication Date: 10/23/2013]